# Standard Controlled Terminology across the Clinical Trial Continuum

Biomedical Informatics without Borders
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**CDISC**

*Setting the
Global Standard
for Medical Research*

CLINICAL DATA INTERCHANGE
STANDARDS CONSORTIUM

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# The CDISC Mission

*To develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare*

Strength *through collaboration.*

# CDISC Snapshot

## Global Standards Developing Organization (SDO)

- Founded 1997; Non-profit formed 2000
- Over 250 organizational members (academia, biopharma, service and technology providers, etc)

- ISO TC 215 Liaison A Organization
- Charter agreement with HL7 since 2001
- Member of Joint Initiative Council for Global Standards Harmonization

- Established Coordinating Committees across North America, Europe & Asia
- Standards downloaded from over 60 countries
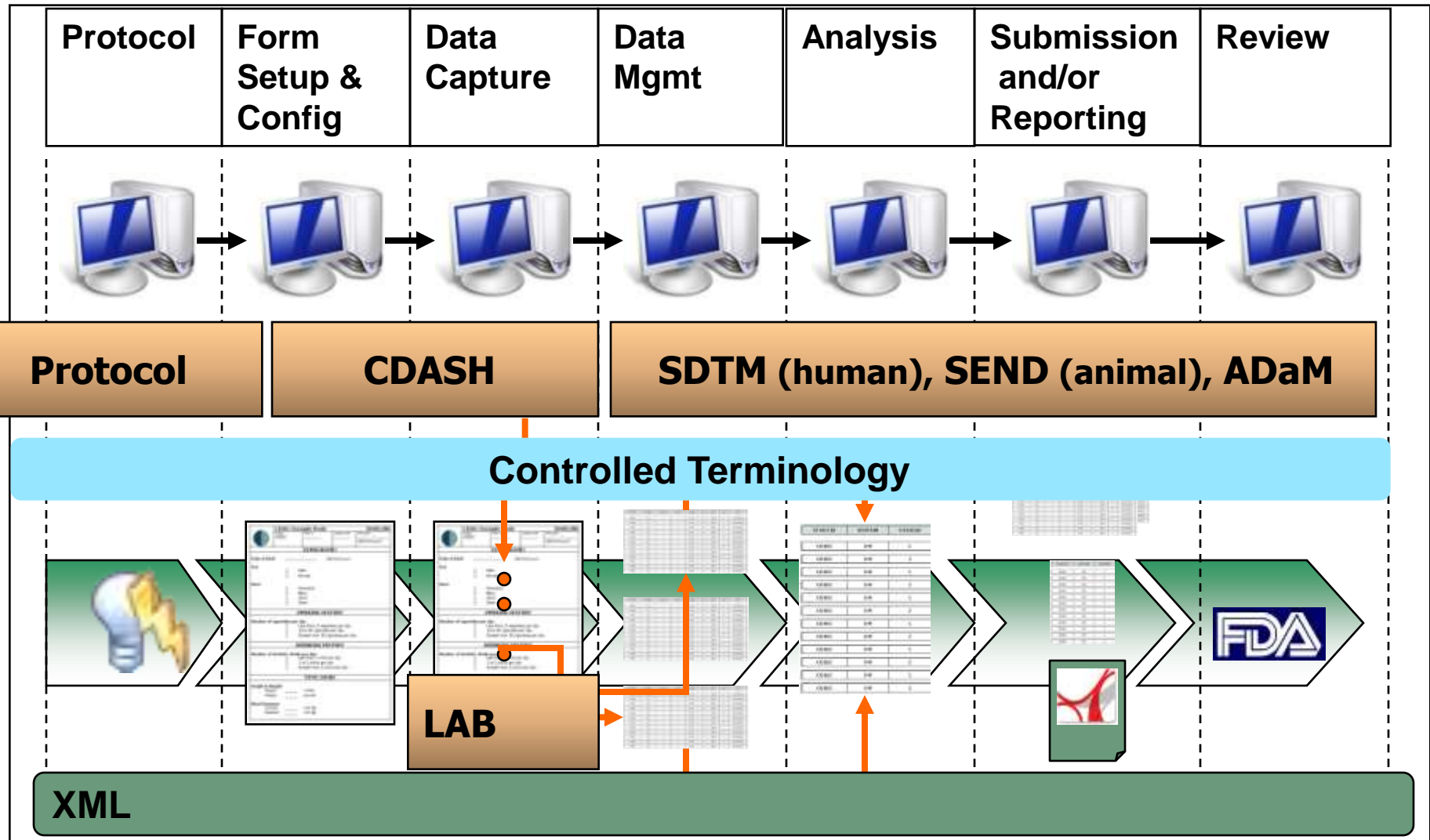
www.cdisc.org

# Global Committees/User Networks

- **CDISC Coordinating Committees**
  - Japan, Europe, China, Korea CDISC Coordinating Committees (J3C, E3C, C3C, K3C)
  - Exploring opportunities in India, Singapore and Southern Hemisphere countries (e.g. Brazil)

- **CDISC User Networks**
  - 9 in United States - regionally located
  - 5 in Europe - language oriented (English, French, German, Italian, Nordic)
  - 2 in China - Beijing & Shanghai
  - 1 in Korea

# CDISC Standards

- Through a consensus-based approach, CDISC has established worldwide industry standards to support the electronic acquisition, exchange, submission and archiving of clinical research data and metadata to improve data quality and streamline medical and biopharmaceutical product development and research processes.

- Standards are freely available on the CDISC website (www.cdisc.org); IP Policy to ensure open standards

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# CDISC Clinical Information Flow

| Protocol | Form Setup & Config | Data Capture | Data Mgmt | Analysis | Submission and/or Reporting | Review |
|----------|---------------------|--------------|-----------|----------|-----------------------------|--------|

**Protocol**

**CDASH**

**SDTM (human), SEND (animal), ADaM**

**Controlled Terminology**

**LAB**

**XML**

# CDISC Terminology Objectives

- ## Primary Objectives

  - – Define and support the terminology needs of CDISC standards from data collection (CDASH) thru regulatory submissions and reporting (SDTM)

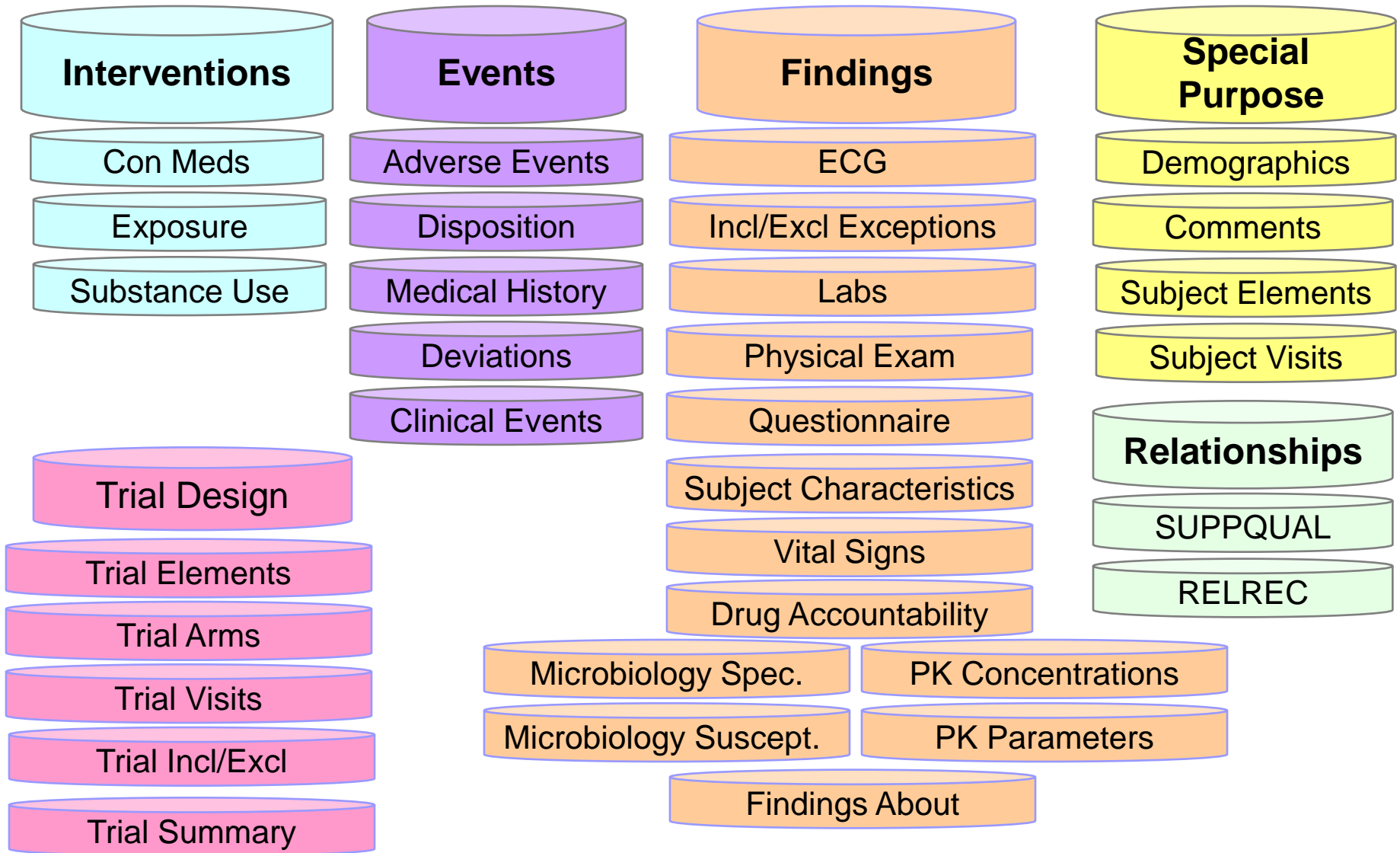  - – Focus on "standard" terminology, definitions codelist development and publication

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# Guiding Principles since 2005

## Adopt…Adapt…Develop Philosophy

- Evaluate and/or utilize existing terminology first

- Expand existing vocabularies where incomplete, working with vocabulary developer / owner

- Harmonize across CDISC Standards and with pre-existing vocabulary initiatives

- Address international needs for global projects and organizations

- Ensure a sustainable "open source" environment and infrastructure for production terminology supporting terminology evolution

# SDTM & CDASH Domains

**Interventions**
- Con Meds
- Exposure
- Substance Use

**Events**
- Adverse Events
- Disposition
- Medical History
- Deviations
- Clinical Events

**Findings**
- ECG
- Incl/Excl Exceptions
- Labs
- Physical Exam
- Questionnaire
- Subject Characteristics
- Vital Signs
- Drug Accountability
- Microbiology Spec.
- Microbiology Suscept.
- PK Concentrations
- PK Parameters
- Findings About

**Special Purpose**
- Demographics
- Comments
- Subject Elements
- Subject Visits

**Relationships**
- SUPPQUAL
- RELREC

**Trial Design**
- Trial Elements
- Trial Arms
- Trial Visits
- Trial Incl/Excl
- Trial Summary

# POSITION Codelist example
## SDTM and CDASH VSPOS, EGPOS

Standard Terminology Codelist

***CDISC Controlled Terminology***

- Sitting
- Prone
- Standing
- Supine
- Fowlers
- Semi-Fowlers
- Trendelenburg
- Reverse Trendelenburg
- Right Lateral Decubitus
- Left Lateral Decubitus

Codelist = Value Set = Permissible Values

# CDISC-NCI EVS Partnership

- Dedicated terminology experts and resources

- CDISC controlled terminology <u>development</u>, <u>harmonization</u>, <u>publication</u> and <u>maintenance</u>

- Established terminology infrastructure and standard operating procedures

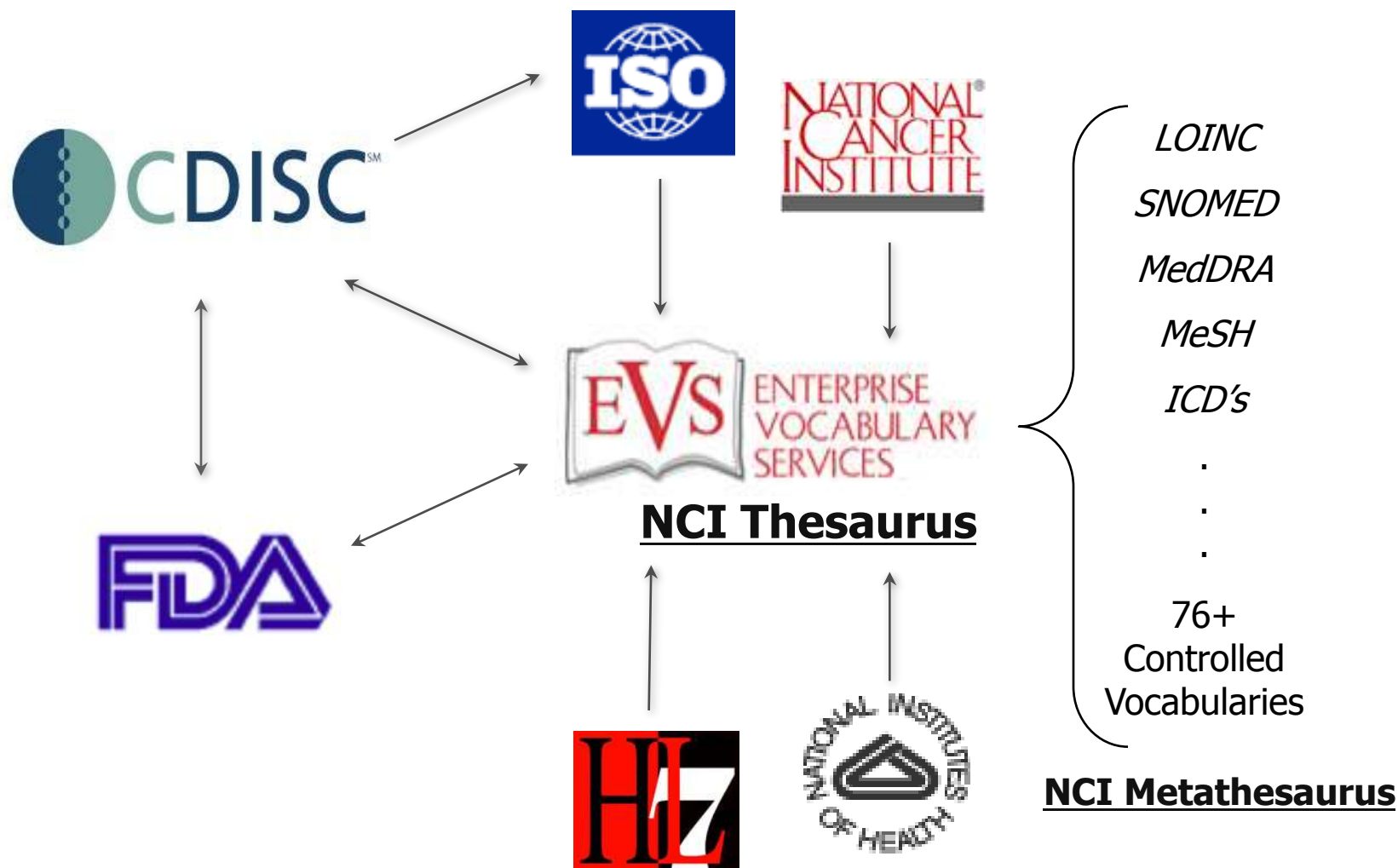- CDISC terms are coded and tagged in *NCI Thesaurus*

# NCI EVS Terminology Services

- Subject Matter Expertise
- Definition writing and analysis
- Terminology tagging and sub-setting
- Terminology coding that ensures cross-harmonization with key partner organizations
- Terminology requests and maintenance
- Links to other controlled terminologies as needed (e.g. FDA, MedDRA, ISO, UCUM etc.)
- Extending into new disease areas

# NCI-CDISC Terminology Alignment



CDISC

ISO

NATIONAL CANCER INSTITUTE

EVS ENTERPRISE VOCABULARY SERVICES
**NCI Thesaurus**

FDA

HL7

NATIONAL INSTITUTES OF HEALTH

*LOINC*

*SNOMED*

*MedDRA*

*MeSH*

*ICD's*

.
.
.

76+
Controlled
Vocabularies

**NCI Metathesaurus**

# Existing CDISC standards currently coded in NCI-EVS NCIt

|  | Numbers | Status |
|---|---|---|
| **CDISC Controlled Terminology** | | |
| SDTM | 3360 | Published |
| CDASH | 82 | Published |
| ADaM | 26 | Published |
| SEND | 1928 | Pilot |
| **CDISC (SDTM+CDASH) Metadata** | | |
| Domains | 45 | Published |
| Observation Classes | 200 | Harmonization |
| Variables | 654 | Harmonization |
| **CDISC Disease Standards Metadata** | | |
| Cardiovascular | 25 | Mapping in EVS |
| Tuberculosis | 130+ | Mapping in EVS |
| Polycystic Kidney Disease | 200+ | Mapping in EVS |

**Published in .xls and .txt for download (.xml coming soon!)**

# Accessing CDISC Terminology

[www.cdisc.org](www.cdisc.org)

ABOUT CDISC | STANDARDS | RESOURCES | NEWS | EDUCATION & EVEN

**STANDARDS**

SDTM

Operational Data Model

Define.XML

Study/Trial Design Model

LAB

ADaM

Protocol

**Terminology**

CDASH

SEND

## Terminology

### Terminology Call for Public Review

Between 1 January and 31 March 2010 (Q1), 46 terminology requests were submitted through the Terminology Request page. The requests have been assessed, addressed and answered as appropriate. The requests are assigned a Level I, II, or III based on the change requested. Level I=spelling fixes, duplication of terms, or minor changes to the definition (3 terms), Level II= synonyms added, significant additions or changes in the meaning of definition (6 terms), Level III= new terms added to an existing codelist and suggestions for new codelists (37 terms). This review contains only 3 terms. The other terms are being considered during the next major terminology review due to complexity. Most of the Level III terms were for new lab terms.

NCI EVS Terminology Resources (access to CDISC, FDA and other terminology)

# Your Standards Experience..?

# Biomedical Informatics without Borders



And…across Federal Agencies, NIH Institutes, etc.

# Strength *through collaboration.*

If you are interested in contributing to the CDISC Terminology
Initiative, please contact me…

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# Disease-specific Standards

- NIH Roadmap Projects 2006-2008
  - Tuberculosis…Pulmonary TB
  - Cardiovascular…Acute Coronary Syndrome

- PKD Foundation 2009-2010
  - Polycystic Kidney Disease: standard clinical data elements, definitions and terminology

- NINDS & CAMD 2009-2010
  - Alzheimer's Disease
  - Parkinson's Disease

- Other Evolving Projects
  - Oncology
  - Imaging and Medical Devices